

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
18 December 2003 (18.12.2003)

PCT

(10) International Publication Number  
**WO 03/103525 A2**

(51) International Patent Classification<sup>7</sup>: **A61B 19/00**

(21) International Application Number: PCT/US03/18255

(22) International Filing Date: 10 June 2003 (10.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/386,758 10 June 2002 (10.06.2002) US  
60/456,552 24 March 2003 (24.03.2003) US

(71) Applicant: **CORBITT, John, D., Jr.** [US/US]; 142 JFK Drive, Atlantis, FL 33462 (US).

(74) Agent: **SOFFEN, Stephen, A.**; Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street NW, Washington, DC 20037-1526 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

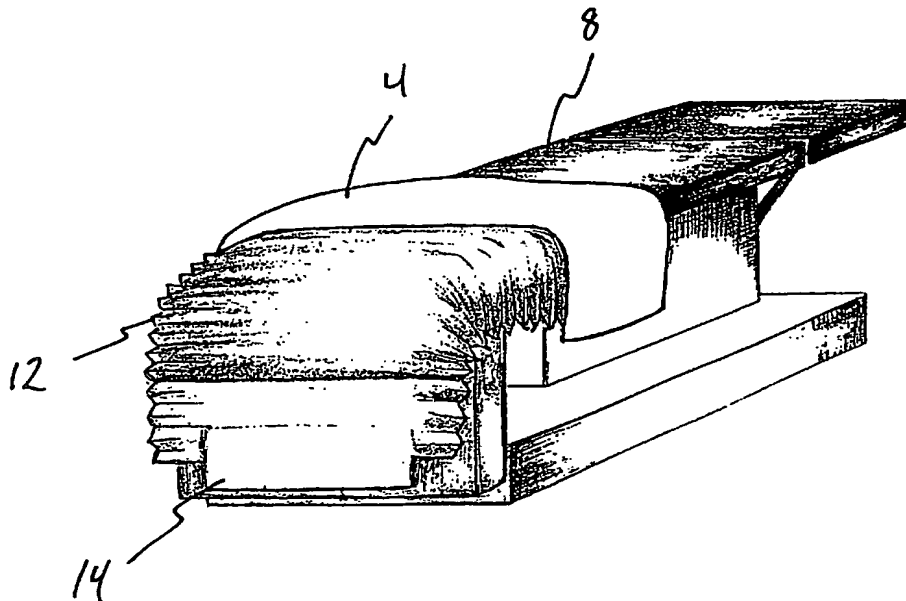
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— without international search report and to be republished upon receipt of that report

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: **SURGICAL DRAPING SYSTEM**



(57) **Abstract:** A surgical draping system separates the sterile surgical field from the unsterile surgical table and isolates the patient so that sterile surgical procedures can be performed without chance of contamination. The components of the surgical draping system are provided folded and in sterile condition inside a sealed bag container. The sealed bag is placed across an operating table prior to placement of the patient. Once the patient has been positioned on the operating table, the bag is opened and the surgical drape is extended. The draping system may include coverings for legs or arms, and a top drape. The draping system isolates the operating field in a simple and sterile manner, and can be discarded at the termination of the procedure.

WO 03/103525 A2

10/ARTS

10/518160  
EV450488661US  
Docket No.: C2002.0001/P001-PC  
DT01 Rec'd PCT/PTC 10 DEC 2004

## SURGICAL DRAPING SYSTEM

### BACKGROUND OF THE INVENTION

[0001] The present invention relates to a sterile surgical draping system for use during surgical procedures. The system could be used, for example, in surgeries on the perineal area, including but not limited to the buttocks, vaginal area, anal area, and upper thighs, or on the torso and upper extremities, including the head and arms. Many procedures are performed in combination with abdominal surgery or solely surgical intervention of these areas, in which case the area requires a sterile, surgical field. Currently, after the patient is placed on the operating table appropriately for surgery, sheets are pushed under the patient which results in random sterilization and inadequate isolation of the patient from the surgical table. The system provides a method of surgery in which, instead of forcing a sheet underneath a patient's buttocks, shoulder, or head, for example, a drape according to the present invention is placed under the patient prior to surgery, and extended to isolate the area of surgical interest from an operating table surface, including operating table extensions, such as leg, shoulder, or head boards.

### SUMMARY OF THE INVENTION

[0002] The draping system of the present invention isolates the surgical area in a sterile fashion and in a manner that overcomes problems with current methods of draping. The draping system includes a sterile flexible drape, made of cloth, plastic, or paper for example, which is folded, preferably, in an accordion fashion, and placed in a sealed bag. The bag preferably is elongated for placing across an operating table or operating surface. The bag also preferably is perforated so that it can easily be torn open or an edge can be separated from the main portion of the bag.

[0003] The folded drape, optionally enclosed in a bag, is laid across the operating table, for example, prior to placing the patient on the table. The patient is then placed on the table so that the folded drape lies beneath the patient. In a surgical procedure involving a perineal area, for example, the folded drape would be located near the lower

lumbar spine region. After the patient has been positioned properly and prepped, the perforated portion of the bag, which is available for access near the edge of the table, is then opened, preferably simply by pulling by hand, to withdraw the interior accordion sterile drape from the inner portion of the bag. The drape is pulled out so that it covers the table in the area of surgical interest and covers substantially the portion of the operating table down toward the floor. Sterile leggings are then placed over the legs of the patient, or in the case of an upper extremity procedure, over one or more of the patient's arm. A top drape with an adhesive strip, for example an abdominal drape with adhesive at the pubic area, also is provided. At the termination of the procedure, the draping system components are discarded. Perforations in the drape are provided to simplify separation and removal of contaminated portions of the drape from those portions of the drape likely to remain in place.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0004] Fig. 1 is a perspective view showing the surgical drape according to an exemplary embodiment of the present invention provided on a surgical table within its original container, with perforations indicated along the leading edge of the sealed package.

[0005] Fig. 2 illustrates the sterile, accordion-folded surgical drape shown in Fig. 1 partially withdrawn from the original container.

[0006] Fig. 3 illustrates an operating room table with the surgical drape of the present invention laying fully extended over the end of the operating table.

[0007] Fig. 4 illustrates a patient being placed on top of the folded surgical drape with the patient's legs in stirrups to facilitate surgery in the local area.

[0008] Fig. 5 illustrates the surgical drape being pulled from its container after the perineum of the patient has been prepped.

[0009] Fig. 6 illustrates the surgical drape in place and fully extended.

[0010] Fig. 7 illustrates the surgical drape in place with leg covers placed over the patient's legs.

[0011] Fig. 8 illustrates a leg or arm cover according to an exemplary embodiment of the present invention.

[0012] Fig. 9 illustrates the cover of Fig. 8 collapsed for packaging.

[0013] Fig. 10 illustrates an abdominal drape according to an exemplary embodiment of the present invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00014] Referring to Fig. 1, a surgical drape assembly 2 is shown. The assembly includes a flexible drape 10. The drape 10 is made of a flexible material, such as cloth, plastic, paper, or other material capable of being provided or rendered sterile for use in a surgical operating arena. The drape is of sufficient length and width to cover an end of an operating table 8. The drape is provided in a folded condition, preferably, in an accordion fashion to compact the drape along its length. The width of the drape extends beyond the side edges of the operating table. The drape optionally is placed in a long, narrow sealed bag 4, which can be placed across the end of the operating table 8 so that it hangs down either side of the table. Bag 4 is provided with perforations 6 for ease of tearing open or separation of the edge from the main portion of the bag.

[00015] Referring to Figs. 1-7, a method of using the perineal drape assembly is described. A patient is not shown in Figs. 2 and 3 for clarity of illustration. The drape 10, optionally contained within sealed bag 4, initially is laid widthwise across surgical table 8 prior to placing a patient on the table. See Fig. 1. One or more strips of tape or adhesive can be provided on the exterior of the bag 4 or on the drape 10 to aid in securing the bag and/or the drape to the operating table. The patient 12 is then placed on the table so that the folded drape lies at the lower lumbar spine region at the edge of the table. See Fig. 4. After the patient has been positioned properly and prepped, the perforated portion 6 of the bag, which is on the edge of the table, or the drape itself, is then pulled to withdraw the

sterile drape 10 from the inner portion of the bag 4. An extension or handle 14 is provided on the leading edge of the drape 10 for ease of deployment. See Figs. 2 and 5.

[00016] Drape 10 is pulled out so that its length covers the table in the area of surgical interest and then covers substantially the entire end of the table down toward the floor, as shown in Figs. 3 and 6. The drape 10 can provide sterile protection underneath the patient's buttocks, and extend from beneath the patient toward the floor, or the bag itself can provide the sterile protection under the patient, with the drape providing the remainder of the sterile environment. An adhesive strip can be provided along one or more edges of the drape 10 to secure the drape and prevent slipping. The adhesive strips preferably are protected prior to use by a removable film. At least one line of perforations 17 is provided across the drape 10. Perforations 17 allow for tearing away a soiled portion of the drape after completion of the surgical procedure, whereby a lower leg portion of the table can be extended to support the patient's legs on an unsoiled surface. Advantageously, the drape 10 also allows for the optional attachment of a catch basin 19, made of plastic, for example, to the drape under the area of surgery, to catch blood and other contaminants.

[00017] Referring to Fig. 7, the draping system of the present invention may include sterile leggings 16. Leggings 16 are placed over the legs of the patient, for example, after the patient is placed in stirrups. Leggings 16 can be enclosed with the rest of the draping system along with or in bag 4. An exemplary embodiment of the leg covers 16 according to the present invention is shown in greater detail in Figs. 8 and 9. The leg covers 16 are shaped like a stocking and have a mouth 18 that is round and open to fit easily over the patient's legs. Advantageously, a stiffener 20 preferably is provided at the mouth of the leg cover 16 to allow the mouth 18 of the leg cover 16 to stay open to facilitate placement of the leg cover over the patient's legs. Prior art leg covers generally are folded, flat, and unnecessarily difficult to slide over a patient's legs. Preferably, the leg covers 16 are at least partially enclosed at a foot end 22, opposite the mouth of the leg cover, to cover the patient's feet. The leggings can include perforations for ease of removal after the procedure. Fig. 9 illustrates the leg cover 16 as it is provided prior to surgery, collapsed for

packaging. The leg cover 16 can be packaged, for example, in bag 4 with other components of the surgical draping system.

[00018] Referring to Fig. 10, an exemplary embodiment of an abdominal drape 30 of the draping system is illustrated. Abdominal drape 30 is a flat sheet with adhesive 32 attached on one end so that the adhesive may be placed across the patient's lower pelvis during the draping, prior to surgery. The opposite end, without the adhesive, is extended towards the patient's head. The abdominal drape lays over the patient and hangs down off the table on either side. At the termination of the procedure, the drape 10, leg covers 16, abdominal drape 30, and bag 4 are discarded.

[00019] While the invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. For example, although the invention has been described in connection with an exemplary embodiment as a perineal draping system, the system is easily adapted for use in other surgical procedures, such as those involving the arms and the head. In addition, the draping system can include various numbers of components, such as more than one drape, for example, for placement underneath either side of a patient in an abdominal procedure. Thus, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the following appended claims.

## CLAIMS

What is claimed as new and desired to be protected by Letters Patent of the United States is:

1. A surgical draping system comprising a flexible drape of sterilizable material, wherein the drape is folded so as to be placed across an operating surface prior to the patient, and pulled so that the drape unfolds to cover the end of the table.

2. The surgical draping system of claim 1, wherein the drape is folded with accordion folds.
3. The surgical draping system of claim 1, wherein a handle extends from a leading edge of the drape.
4. The surgical draping system of claim 1, further comprising a bag containing the folded drape.
5. The surgical draping system of claim 4, further comprising an adhesive on the bag for securing the bag to the operating table.
6. The surgical draping system of claim 1, further comprising a pair of leggings to be placed over the legs of the patient.
7. A method of isolating a patient from the operating table in surgical procedures using a surgical draping system, the method comprising:  
placing a folded surgical drape on the operating table; and  
unfolding the folded surgical drape to isolate the patient from the operating table.
8. The method of claim 7, wherein the patient is placed on the surgical drape prior to unfolding the drape.
9. The method of claim 7, further comprising placing coverings on at least one extremity of the patient.
10. The method of claim 7, further comprising placing an top drape on the patient.

## ABSTRACT

A surgical draping system separates the sterile surgical field from the unsterile surgical table and isolates the patient so that sterile surgical procedures can be performed without chance of contamination. The components of the surgical draping system are provided folded and in sterile condition inside a sealed bag container. The sealed bag is placed across an operating table prior to placement of the patient. Once the patient has been positioned on the operating table, the bag is opened and the surgical drape is extended. The draping system may include coverings for legs or arms, and a top drape. The draping system isolates the operating field in a simple and sterile manner, and can be discarded at the termination of the procedure.

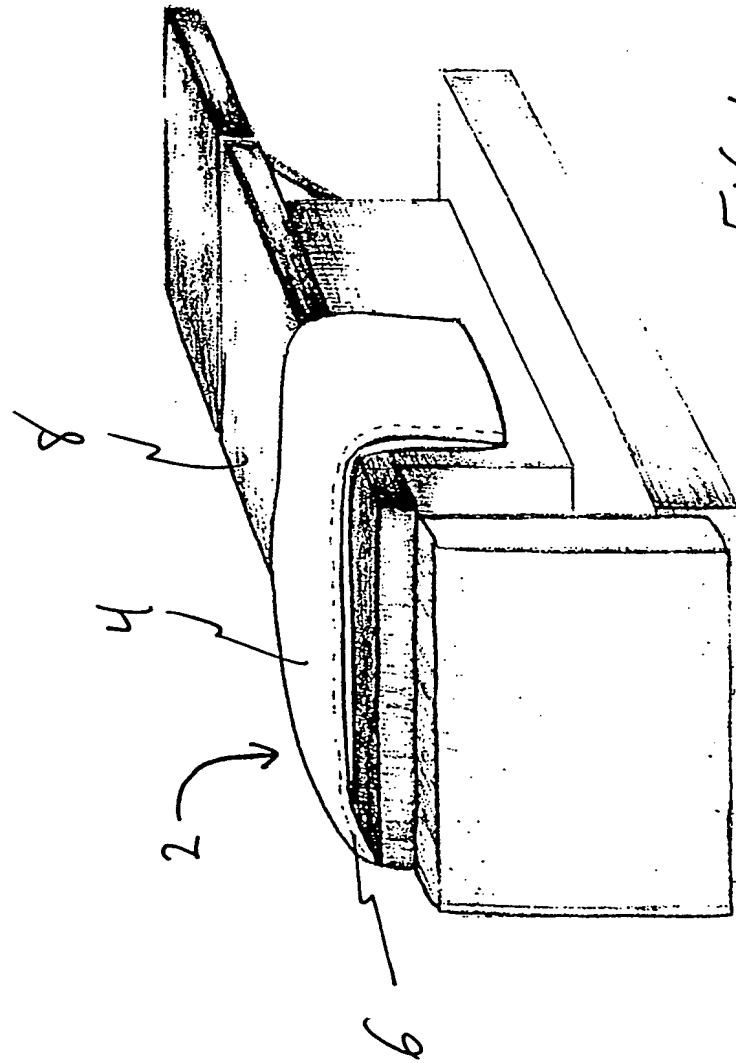
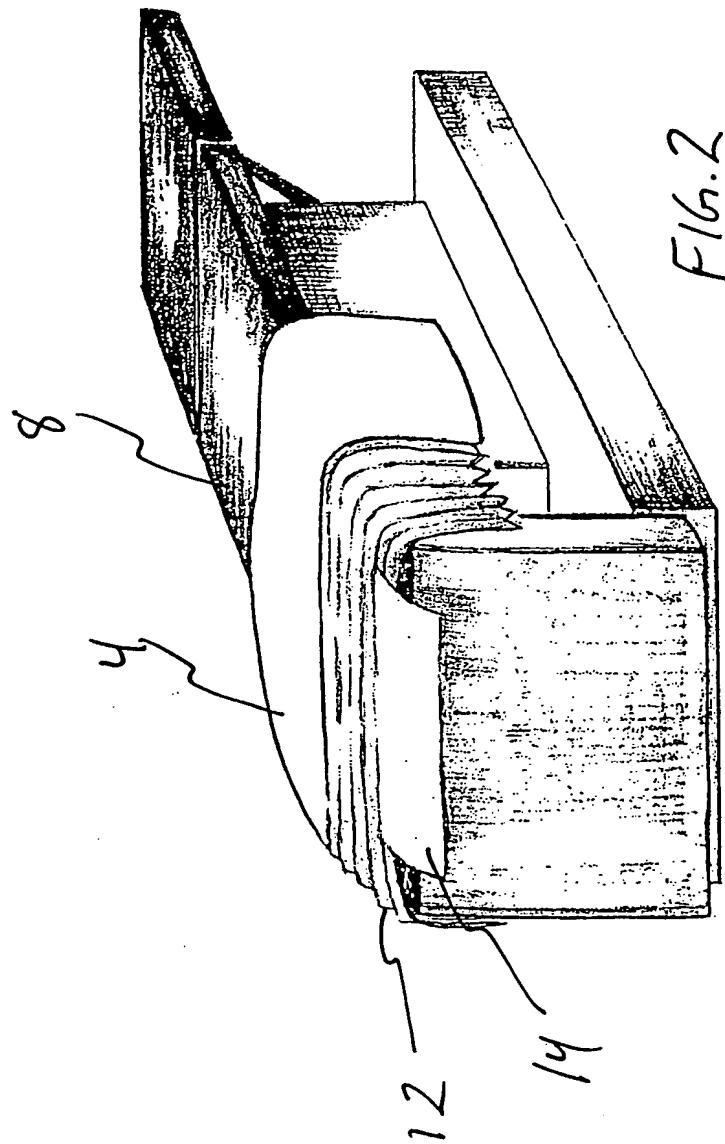
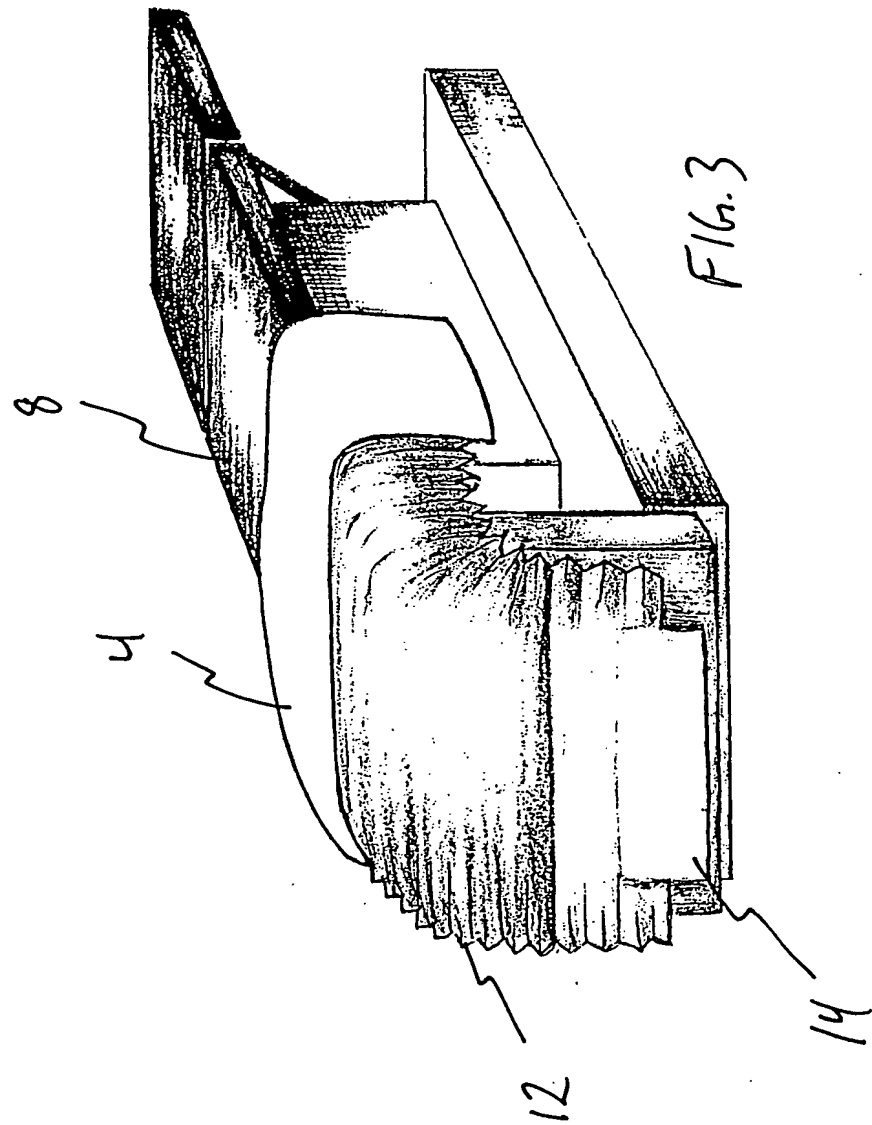


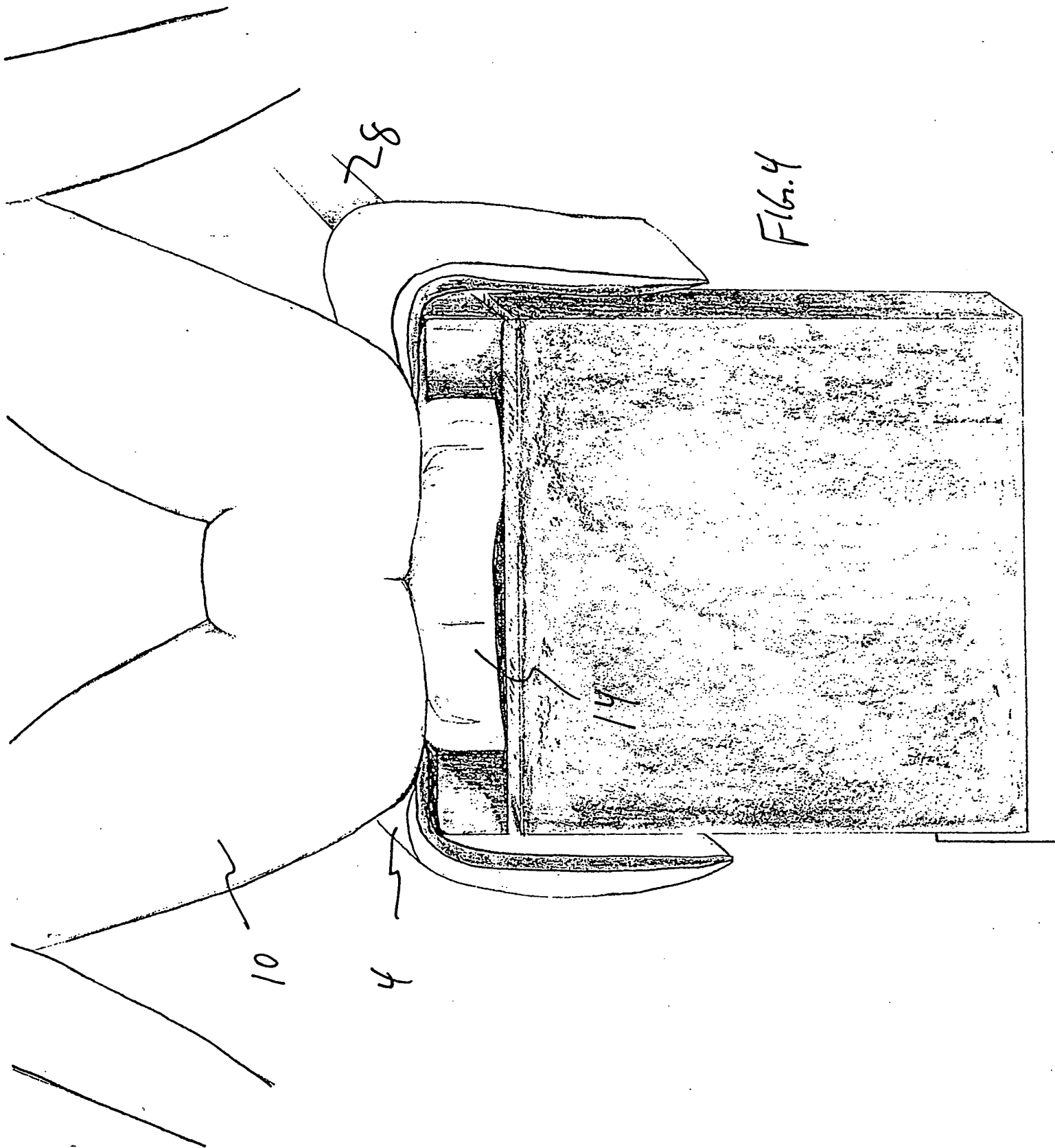
FIG. 1

10/518160





10/518160



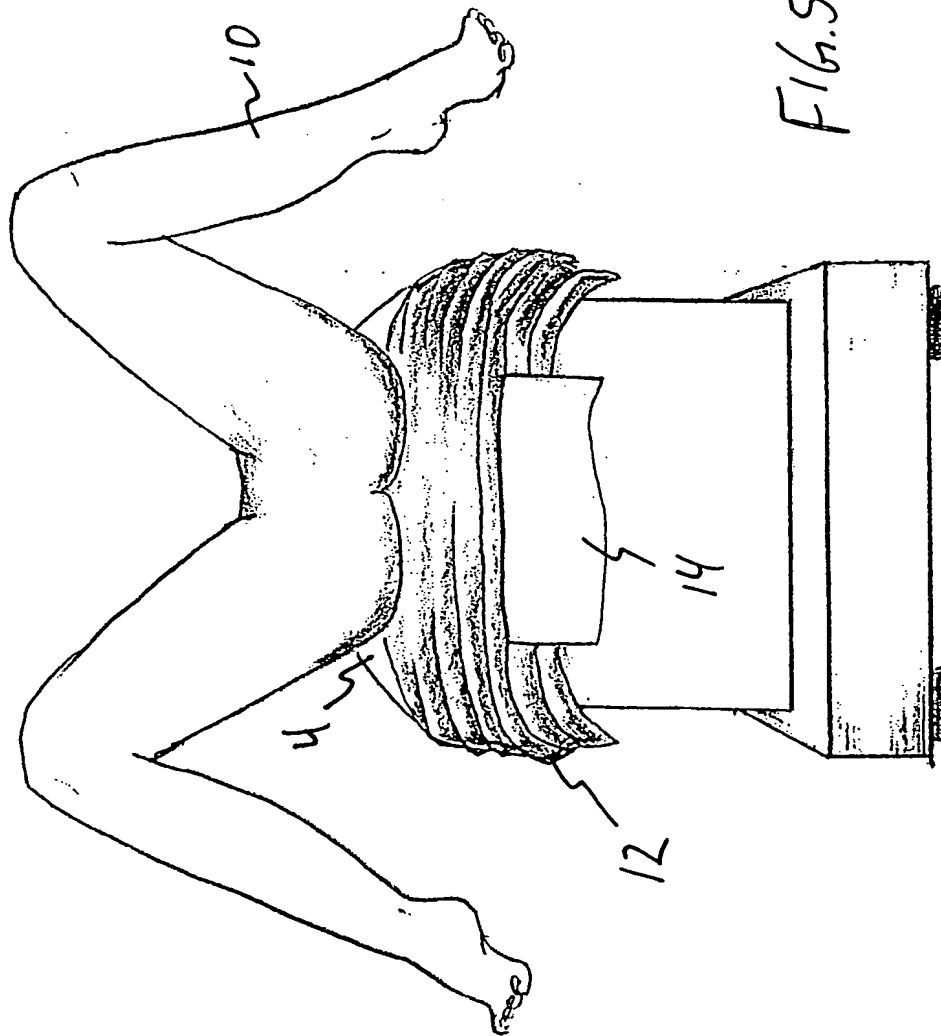
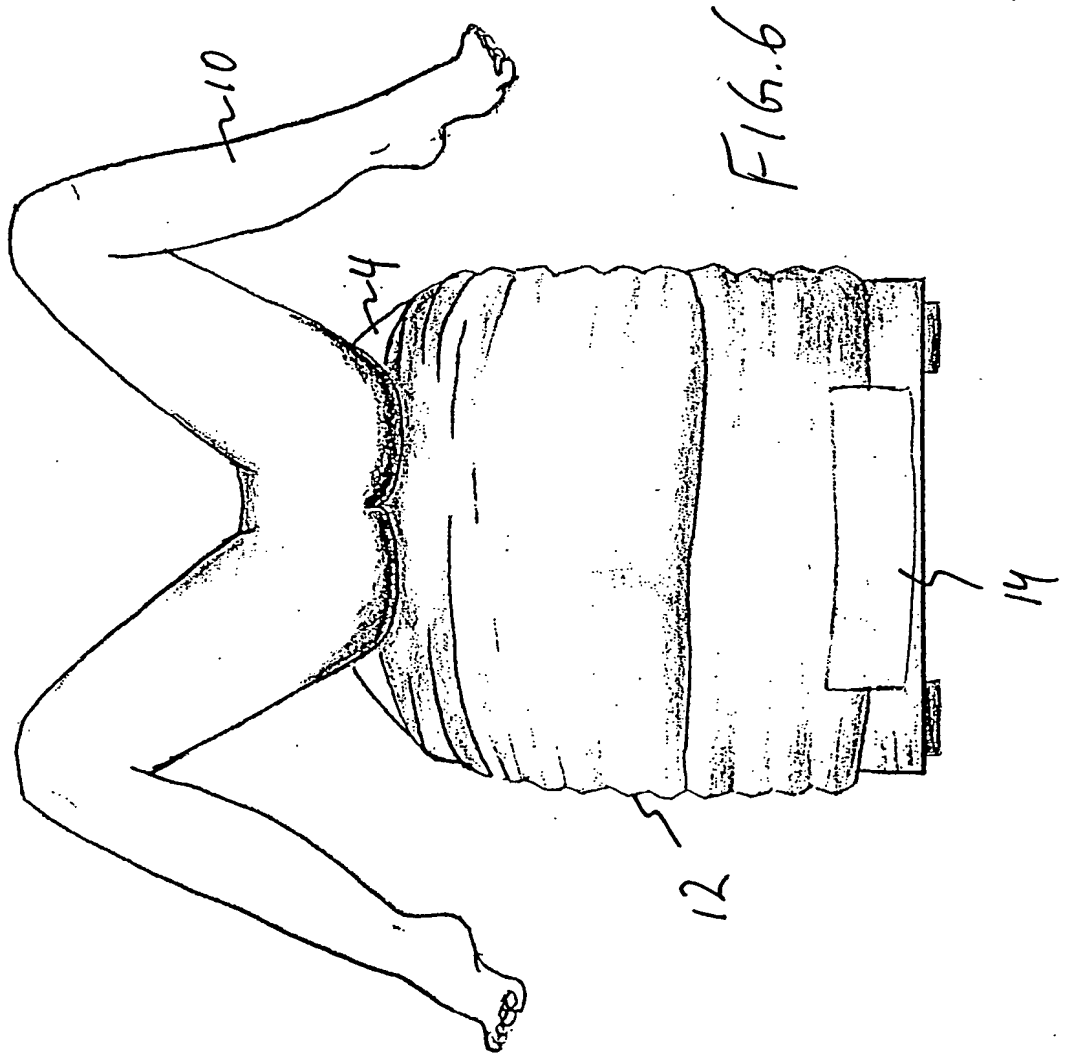
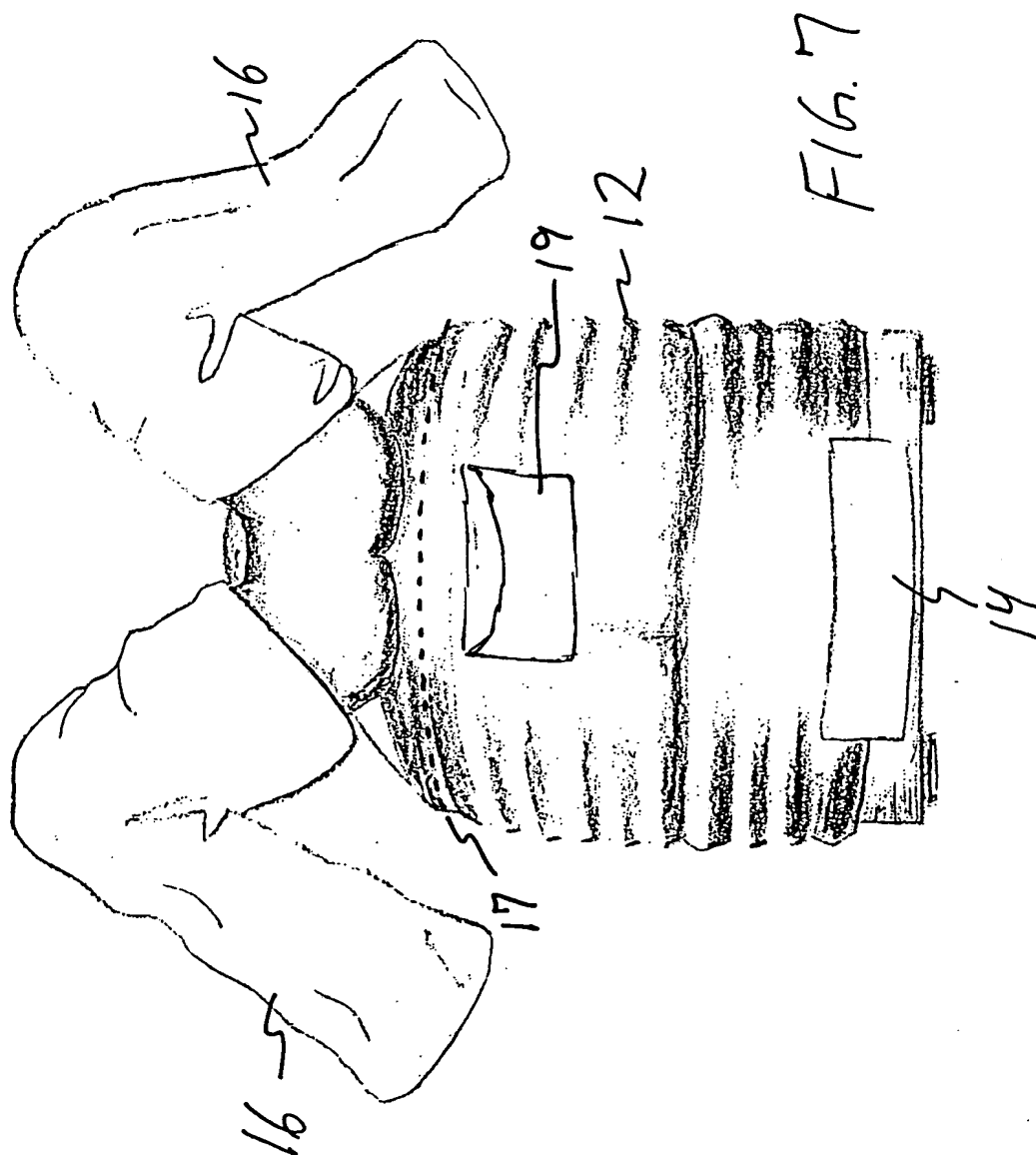


FIG. 5





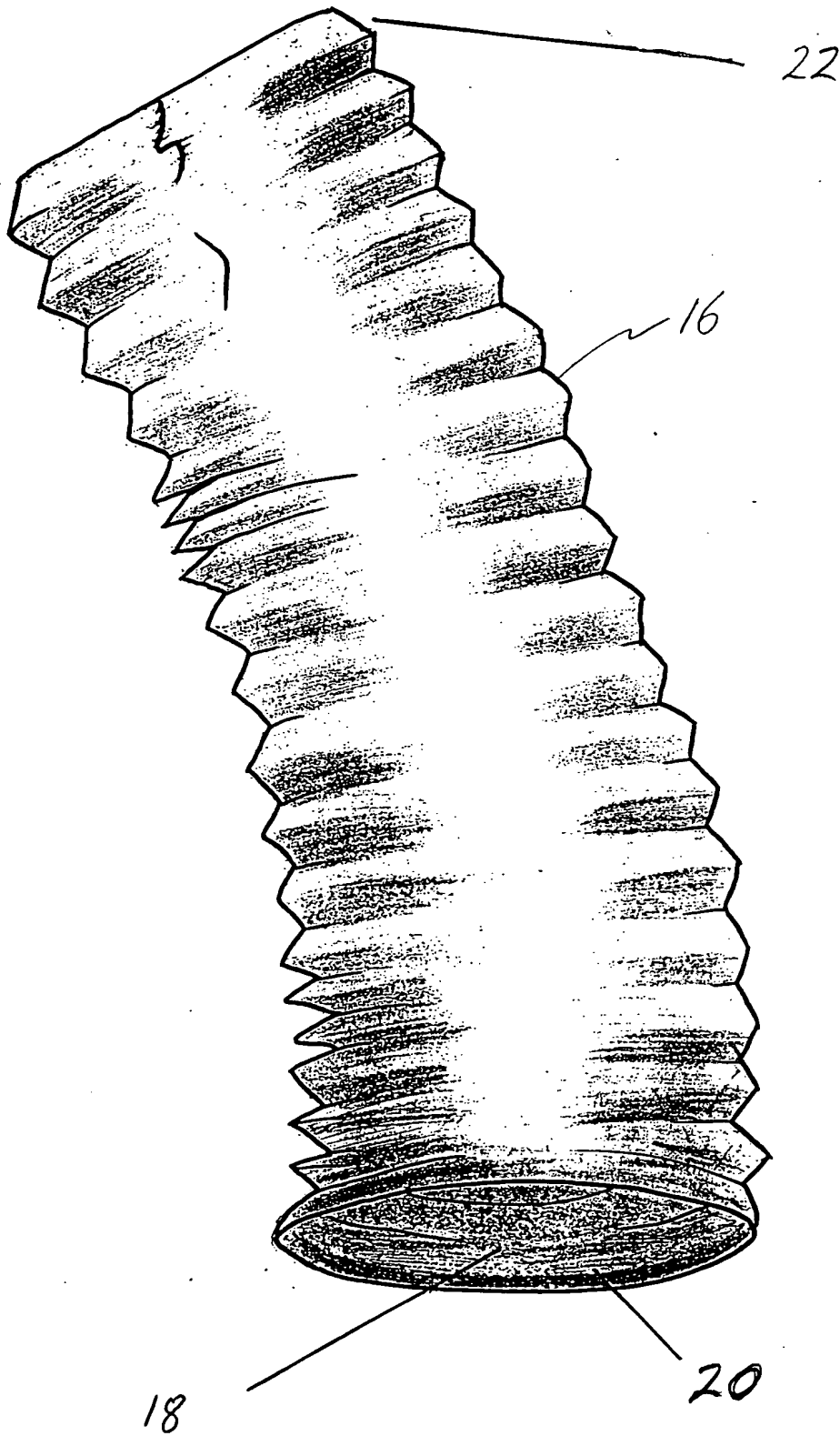


FIG. 8

10/518160

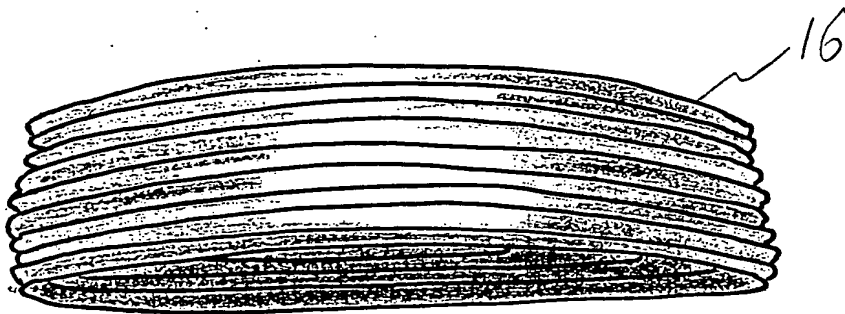
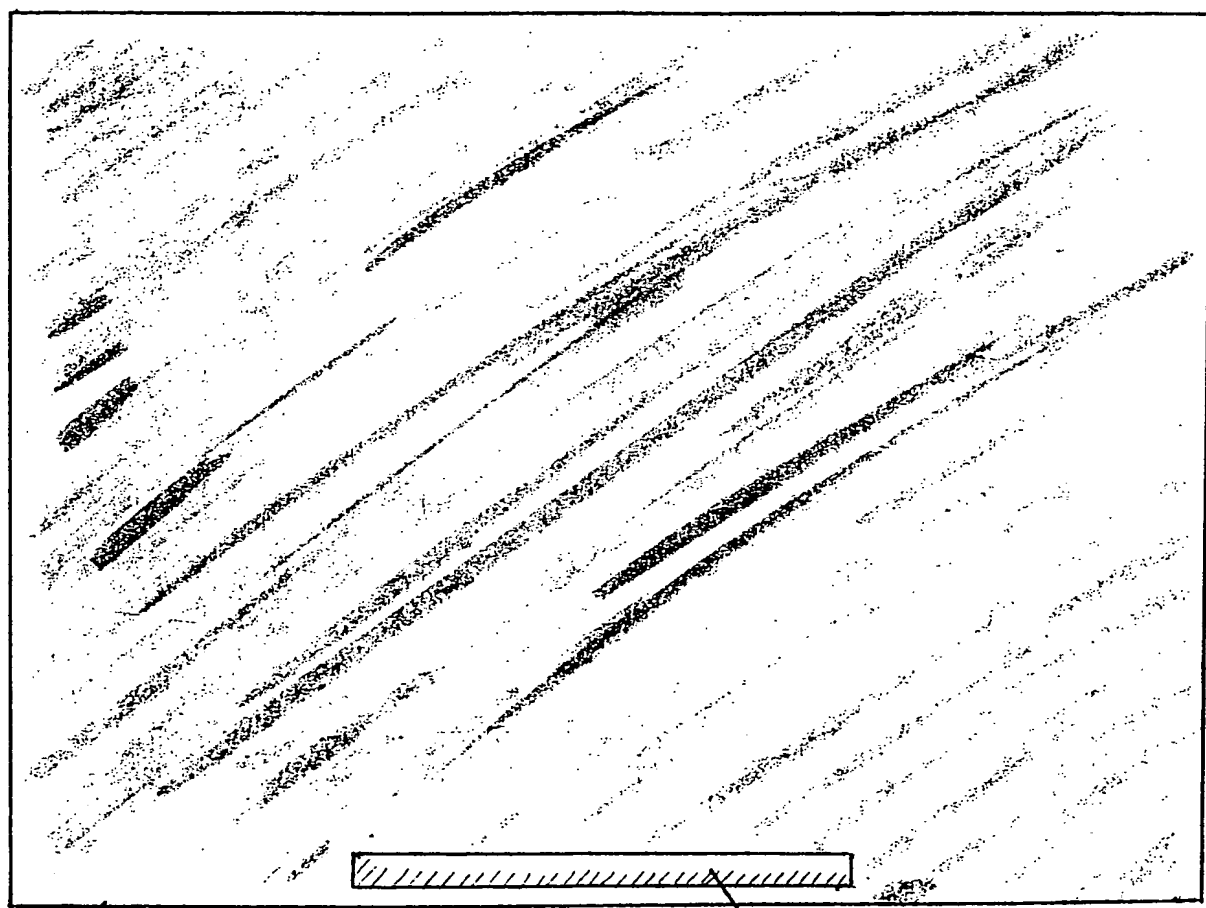


FIG. 9

10/518160



30

FIG. 10

32

Rec'd PCT/PTO 10 DEC 2004

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/18255

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 19/00

US CL : 128/849

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/849-856

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,479,492 A (SINGER) 30 October 1984, see the entire document	1-3 and 7-10
---		
Y		4, 6
Y	US 4,352,429 A (NEWMAN) 05 October 1982, see the entire document	4
Y	US 3,693,618 A (MADDEN) 26 September 1972. See the entire document	6

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

05 November 2003 (05.11.2003)

Date of mailing of the international search report

15 NOV 2003

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703)305-3230

Authorized officer

Nick Lucchesi

Telephone No. 308-0858